GE Healthcare

BiliSoft™ LED Phototherapy System

Service Manual

M1110150 006

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About this Manual

Conventions

Various types of pictures or icons are used in this service manual wherever they reinforce the printed message to alert you to potential safety hazards in one of the following ways:

WARNING:
A WARNING statement is used when the possibility of injury to the patient or the operator exists.

CAUTION:
A CAUTION statement is used when the possibility of damage to the equipment exists.

SENSITIVE TO ELECTROSTATIC DISCHARGE CAUTION
An Electrostatic Discharge (ESD) Susceptibility symbol is displayed to alert service personnel that the part(s) are sensitive to electrostatic discharge and that static control procedures must be used to prevent damage to the equipment.

NOTE: A Note provides additional information to clarify a point in the text.

Repair Policy

CAUTION:
The procedures described in this service manual should be performed by trained and authorized personnel only. Maintenance should only be undertaken by competent individuals who have a general knowledge of and experience with devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications. Genuine replacement parts manufactured or sold by GE Healthcare must be used for all repairs. Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure. After repair, test the equipment to ascertain that it complies with the published specifications.

CAUTION:
This static control precaution symbol appears throughout this manual. When this symbol appears next to a procedure in this manual, static control precautions MUST be observed. Ensure that static charges are safely conducted to ground and not through static sensitive devices.

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Do not use malfunctioning equipment. If the unit is under warranty, contact GE technical support at the number on the back of the manual PRIOR to performing any repairs on the unit.

Service Manual Language

(BG)

ПРЕДУПРЕЖДЕНИЕ

Това упътване за работа е налично само на английски език.

- Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод.
- Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа.
- Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациента в резултат на токов удар, механична или друга опасност.

(ZH-CN)

警告

本维修手册仅提供英文版本。

- 如果客户的维修服务人员需要非英文版本，则客户需自行提供翻译服务。
- 未详细阅读和完全理解本维修手册之前，不得进行维修。
- 忽略本警告可能对维修服务人员、操作人员或患者造成电击、机械伤害或其他形式的伤害。

(ZH-HK)

警告

本服務手冊僅提供英文版本。

- 倘若客戶的服務供應商需要英文以外之服務手冊，客戶有責任提供翻譯服務。
- 除非已參閱本服務手冊及明白其內容，否則切勿嘗試維修設備。
- 不遵從本警告或會令服務供應商、網絡供應商或病人受到觸電、機械性或其他的危險。

(ZH-TW)

警告

本維修手冊僅有英文版。

- 若客戶的維修廠商需要英文版以外的語言，應由客戶自行提供翻譯服務。
- 請勿試圖維修本設備，除非 您已查閱並瞭解本維修手冊。
- 若未留意本警告，可能導致維修廠商、操作員或病患因觸電、機械或其他危險而受傷。

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(HR)

UPOZORENJE

Ovaj servisni priručnik dostupan je na engleskom jeziku.

- Ako davatelj usluge klijenta treba neki drugi jezik, klijent je dužan osigurati prijevod.
- Ne pokušavajte servisirati opremu ako niste u potpunosti pročitali i razumjeli ovaj servisni priručnik.
- Zanemarite li ovo upozorenje, može doći do ozljede davatelja usluge, operatera ili pacijenta uslijed strujnog udara, mehaničkih ili drugih rizika.

(CS)

VÝSTRAHA

Tento provozní návod existuje pouze v anglickém jazyce.

- V případě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka.
- Nesnažte se o údržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah.
- V případě nedodržování této výstrahy může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.

(DA)

ADVARSEL

Denne servicemanual findes kun på engelsk.

- Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse.
- Forsøg ikke at servicere udstyret uden at læse og forstå denne servicemanual.
- Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk stød, mekanisk eller anden fare for teknikeren, operatøren eller patienten.

(NL)

WAARSCHUWING

Deze onderhoudshandleiding is enkel in het Engels verkrijgbaar.

- Als het onderhoudspersoneel een andere taal vereist, dan is de klant verantwoordelijk voor de vertaling ervan.
- Probeer de apparatuur niet te onderhouden alvorens deze onderhoudshandleiding werd geraadpleegd en begrepen is.
- Indien deze waarschuwing niet wordt opgevolgd, zou het onderhoudspersoneel, de operator of een patiënt gewond kunnen raken als gevolg van een elektrische schok, mechanische of andere gevaren.

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(EN)

WARNING:

This service manual is available in English only.

- If a customer's service provider requires a language other than English, it is the customer's responsibility to provide translation services.
- Do not attempt to service the equipment unless this service manual has been consulted and is understood.
- Failure to heed this warning may result in injury to the service provider, operator, or patient from electric shock, mechanical hazards, or other hazards.

(ET)

HOIATUS

See teenindusjuhend on saadaval ainult inglise keeles

- Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tõlketeenuse osutamise eest.
- Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist.
- Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.

(FI)

VAROITUS

Tämä huolto-ohje on saatavilla vain englanniksi.

- Jos asiakkaan huoltohenkilöstö vaatii muuta kuin englanninkielistä materiaalia, tarvittavan käännöksen hankkiminen on asiakkaan vastuulla.
- Älä yritä korjata laitteistoa ennen kuin olet varmasti lukenut ja ymmärtänyt tämän huolto-ohjeen.
- Mikäli tätä varoitusta ei noudateta, seurauksena voi olla huoltohenkilöstön, laitteiston käyttäjän tai potilaan vahingoittuminen sähköiskun, mekaanisen vian tai muun vaaratilanteen vuoksi.

(FR)

ATTENTION

Ce manuel d'installation et de maintenance est disponible uniquement en anglais.

- Si le technicien d'un client a besoin de ce manuel dans une langue autre que l'anglais, il incombe au client de le faire traduire.
- Ne pas tenter d'intervenir sur les équipements tant que ce manuel d'installation et de maintenance n'a pas été consulté et compris.
- Le non-respect de cet avertissement peut entraîner chez le technicien, l'opérateur ou le patient des blessures dues à des dangers électriques, mécaniques ou autres.

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(DE)

WARNUNG

Diese Serviceanleitung existiert nur in englischer Sprache.

- Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.
- Versuchen Sie nicht diese Anlage zu warten, ohne diese Serviceanleitung gelesen und verstanden zu haben.
- Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.

(EL)

ΠΡΟΕΙΔΟΠΟΙΗΣΗ

Το παρόν εγχειρίδιο σέρβις διατίθεται μόνο στα αγγλικά.

- Εάν ο τεχνικός σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει τις υπηρεσίες μετάφρασης.
- Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό αν δεν έχετε συμβουλευτεί και κατανοήσει το παρόν εγχειρίδιο σέρβις.
- Αν δεν προσέξετε την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στον τεχνικό σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.

(HU)

FIGYELMEZTETÉS

Ezen karbantartási kézikönyv kizárólag angol nyelven érhető el.

- Ha a vevő szolgáltatója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése.
- Ne próbálja elkezdeni használni a berendezést, amíg a karbantartási kézikönyvben leírtakat nem értelmezték.
- Ezen figyelmeztetés figyelmen kívül hagyása a szolgáltató, működtető vagy a beteg áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.

(IS)

AÐVÖRUN

Þessi þjónustuhandbók er aðeins fáanleg á ensku.

- Ef að þjónustuveitandi viðskiptamanns þarfnast annas tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálaþjónustu.
- Reynið ekki að afgreiða tækið nema að þessi þjónustuhandbók hefur verið skoðuð og skilin.
- Brot á sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklings frá raflosti, vélrænu eða öðrum áhættum.

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(IT)

AVVERTENZA

Il presente manuale di manutenzione è disponibile soltanto in lingua inglese.

- Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.
- Procedere alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.
- Il mancato rispetto della presente avvertenza potrebbe causare lesioni all'addetto alla manutenzione, all'operatore o ai pazienti provocate da scosse elettriche, urti meccanici o altri rischi.

(JA)

警告

このサービスマニュアルには英語版しかありません。

- **サービスを担当される業者が英語以外の言語を要求される場合、翻訳作業はその業者の責任で行うものとさせていただきます。**
- **このサービスマニュアルを熟読し理解せずに、装置のサービスを行わないでください。**
- **この警告に従わない場合、サービスを担当される方、操作員あるいは患者 さんが、感電や機械的又はその他の危険により負傷する可能性があります。**

(KO)

경고

본 서비스 매뉴얼은 영어로만 이용하실 수 있습니다.

- 고객의 서비스 제공자가 영어 이외의 언어를 요구할 경우, 번역 서비스를 제공하는 것은 고객의 책임입니다.
- 본 서비스 매뉴얼을 참조하여 숙지하지 않은 이상 해당 장비를 수리하려고 시도하지 마십시오.
- 본 경고 사항에 유의하지 않으면 전기 쇼크, 기계적 위험, 또는 기타 위험으로 인해 서비스 제공자, 사용자 또는 환자에게 부상을 입힐 수 있습니다.

(LV)

BRĪDINĀJUMS

Šī apkopes rokasgrāmata ir pieejama tikai angļu valodā.

- Ja klienta apkopes sniedzējam nepieciešama informācija citā valodā, klienta pienākums ir nodrošināt tulkojumu.
- Neveiciet aprīkojuma apkopi bez apkopes rokasgrāmatas izlasīšanas un saprašanas.
- Šī brīdinājuma neievērošanas rezultātā var rasties elektriskās strāvas trieciena, mehānisku vai citu faktoru izraisītu traumu risks apkopes sniedzējam, operatoram vai pacientam.

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(LT)

ĮSPĖJIMAS

Šis eksploatavimo vadovas yra tik anglų kalba.

- Jei kliento paslaugų tiekėjas reikalauja vadovo kita kalba – ne anglų, suteikti vertimo paslaugas privalo klientas.
- Nemėginkite atlikti įrangos techninės priežiūros, jei neperskaitėte ar nesupratote šio eksploatavimo vadovo.
- Jei nepaisysite šio įspėjimo, galimi paslaugų tiekėjo, operatoriaus ar paciento sužalojimai dėl elektros šoko, mechaninių ar kitų pavojų.

(NO)

ADVARSEL

Denne servicehåndboken finnes bare på engelsk.

- Hvis kundens serviceleverandør har bruk for et annet språk, er det kundens ansvar å sørge for oversettelse.
- Ikke forsøk å reparere utstyret uten at denne servicehåndboken er lest og forstått.
- Manglende hensyn til denne advarselen kan føre til at serviceleverandøren, operatøren eller pasienten skades på grunn av elektrisk støt, mekaniske eller andre farer.

(PL)

OSTRZEŻENIE

Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim.

- Jeśli serwisant klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta.
- Nie próbować serwisować urządzenia bez zapoznania się z niniejszym podręcznikiem serwisowym i zrozumienia go.
- Niezastosowanie się do tego ostrzeżenia może doprowadzić do obrażeń serwisanta, operatora lub pacjenta w wyniku porażenia prądem elektrycznym, zagrożenia mechanicznego bądź innego.

(PT-BR)

AVISO

Este manual de assistência técnica encontra-se disponível unicamente em inglês.

- Se outro serviço de assistência técnica solicitar a tradução deste manual, caberá ao cliente fornecer os serviços de tradução.
- Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.
- A não observância deste aviso pode ocasionar ferimentos no técnico, operador ou paciente decorrentes de choques elétricos, mecânicos ou outros.

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(PT-PT)

ATENÇÃO

Este manual de assistência técnica só se encontra disponível em inglês.

- Se qualquer outro serviço de assistência técnica solicitar este manual noutro idioma, é da responsabilidade do cliente fornecer os serviços de tradução.
- Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica.
- O não cumprimento deste aviso pode colocar em perigo a segurança do técnico, do operador ou do paciente devido a choques eléctricos, mecânicos ou outros.

(RO)

ATENȚIE

Acest manual de service este disponibil doar în limba engleză.

- Dacă un furnizor de servicii pentru clienți necesită o altă limbă decât cea engleză, este de datoria clientului să furnizeze o traducere.
- Nu încercați să reparați echipamentul decât ulterior consultării şi înțelegerii acestui manual de service.
- Ignorarea acestui avertisment ar putea duce la rănirea depanatorului, operatorului sau pacientului în urma pericolelor de electrocutare, mecanice sau de altă natură.

(RU)

ОСТОРОЖНО!

Данное руководство по техническому обслуживанию представлено только на английском языке.

- Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует самостоятельно обеспечить перевод.
- Перед техническим обслуживанием оборудования обязательно обратитесь к данному руководству и поймите изложенные в нем сведения.
- Несоблюдение требований данного предупреждения может привести к тому, что специалист по техобслуживанию, оператор или пациент получит удар электрическим током, механическую травму или другое повреждение.

(SR)

UPOZORENJE

Ovo servisno uputstvo je dostupno samo na engleskom jeziku.

- Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge.
- Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo.
- Zanemarivanje ovog upozorenja može dovesti do povređivanja servisera, rukovaoca ili pacijenta usled strujnog udara ili mehaničkih i drugih opasnosti.

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(SK)

UPOZORNENIE

Tento návod na obsluhu je k dispozícii len v angličtine.

- Ak zákazníkov poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka.
- Nepokúšajte sa o obsluhu zariadenia, kým si neprečítate návod na obluhu a neporozumiete mu.
- Zanedbanie tohto upozornenia môže spôsobiť zranenie poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanické alebo iné ohrozenie.

(ES)

ATENCION

Este manual de servicio sólo existe en inglés.

- Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual.
- No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.
- La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.

(SV)

VARNING

Den här servicehandboken finns bara tillgänglig på engelska.

- Om en kunds servicetekniker har behov av ett annat språk än engelska, ansvarar kunden för att tillhandahålla översättningstjänster.
- Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken.
- Om du inte tar hänsyn till den här varningen kan det resultera i skador på serviceteknikern, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.

(SL)

OPOZORILO

Ta servisni priročnik je na voljo samo v angleškem jeziku.·

- Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod.·
- Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli.·
- Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.

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(TR)

DİKKAT

Bu servis kılavuzunun sadece ingilizcesi mevcuttur.

- Eğer müşteri teknisyeni bu kılavuzu ingilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer.
- Servis kılavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz.
- Bu uyarıya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.

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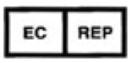
Chapter 1: Safety Information

Symbol Definitions

This section identifies the symbols that are displayed on the BiliSoft unit:

Symbol	Description
~	Indicates alternating current.
	Indicates IEC Type B equipment.
T	This letter appearing before a fuselink value indicates a time delay fuselink.
	Cover patient's eyes during phototherapy.
	On/Off Standby Switch
	Unit overheated indicator
	Hour meter
	LED failure indicator
	Do not spray cleaner directly onto the fiberoptic lenses. The fiberoptic lenses require special cleaning methods. See cleaning section of this manual for complete details.
	See the Operation Manual for more information.
	European Union Representative
	Manufacturer

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Symbol	Description
	ETL symbol
	CE mark
	WEEE symbol
	Ground/Earthing

General Safety Information

WARNING:
Side Effects: Looking at light emitted by any phototherapy device for prolonged periods may cause side effects, such as headache, nausea, or mild vertigo.

WARNING:
Flammable Solutions: Never use flammable solutions to clean the BiliSoft LED Phototherapy System or any of its parts.

CAUTION

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the service manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

The BiliSoft LED Phototherapy System should not be used adjacent to or be stacked on other equipment. If adjacent or stacked use is necessary, the BiliSoft LED Phototherapy System should be observed to verify normal operation in the configuration in which it will be used.

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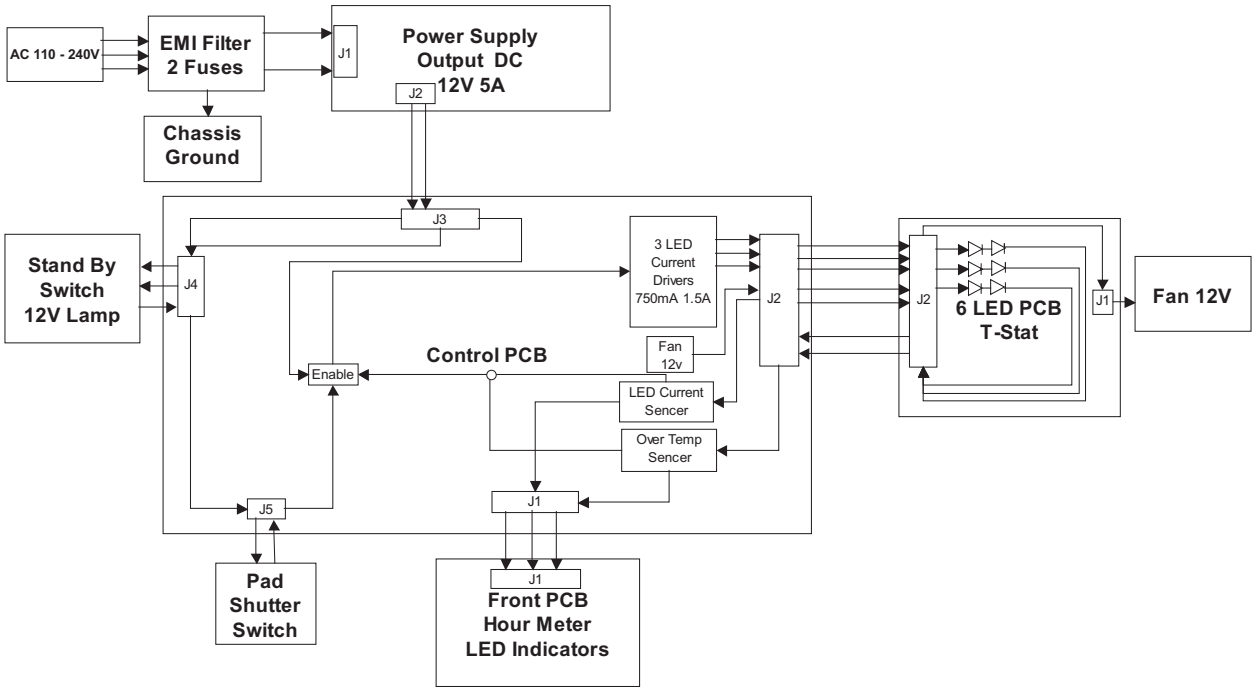
Chapter 2: Functional Description



AC power is fused and filtered by the EMI Filter before it is converted to 12V DC by the Power Supply and delivered to the Control PCB. The Control PCB consists of three identical buck regulator circuits that are configured as constant voltage/constant current sources with the ability to adjust the constant current source output to the LED's. The Control PCB drives three pairs of LED's on the LED PCB and the 12V fan. The LED PCB is only enabled when power is supplied, the Standby Switch is "On", the Pad Shutter Switch is closed and the solid-state thermostat on the LED PCB is not tripped. When the solid-state thermostat on the LED PCB is tripped, the fan still gets 12V to help cool the box. The Control PCB also delivers 12V to the Standby Switch lamp. When the LED current sensor on the Control PCB detects that at least one pair of LED's is not working properly, the LED module failure indicator on the Front PCB blinks. When the thermostat on the LED PCB is tripped, the unit overheated indicator on the Front PCB lights. Whenever power to the LED PCB is "enabled", the hour meter gets the signal to count hours. See the schematic on the following page for more detail.

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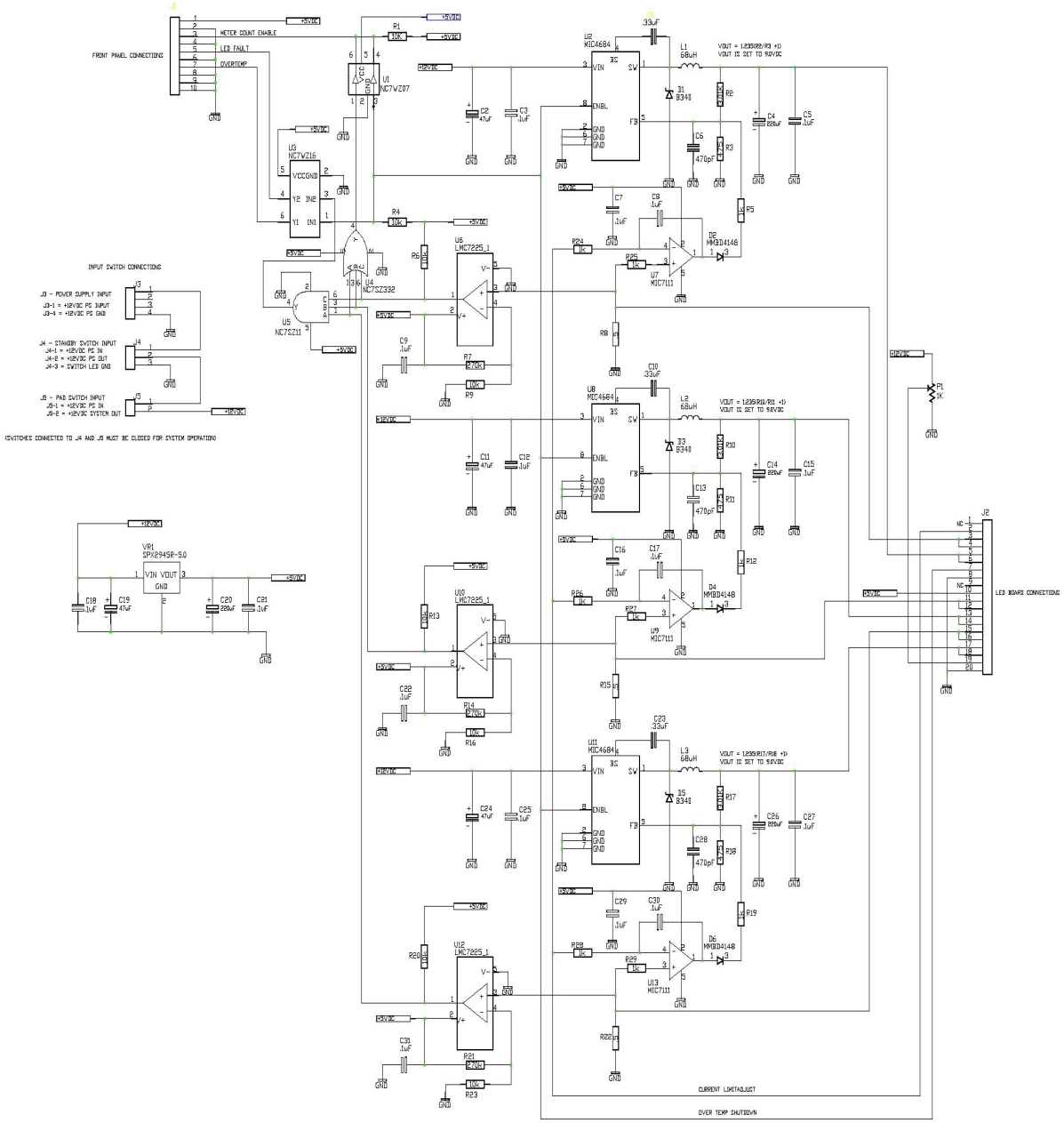
FRONT PANEL CONNECTIONS
METER COUNT ENABLE
LED FAULT
OVERTEMP
INPUT SWITCH CONNECTIONS
J3 - POWER SUPPLY INPUT
J3-1 = +12VDC PS INPUT
J3-4 = +12VDC PS GND
J4 - STANDBY SWITCH INPUT
J4-1 = +12VDC PS IN
J4-2 = +12VDC PS OUT
J4-3 = SWITCH LED GND
J5 - PAB SWITCH INPUT
J5-1 = +12VDC PS IN
J5-2 = +12VDC SYSTEM OUT
SWITCHES CONNECTED TO J4 AND J5 MUST BE CLOSED FOR SYSTEM OPERATION
LED BOARD CONNECTIONS
CURRENT LIMIT ADJUST
OVER TEMP SHUTDOWN

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Chapter 3: Components and User Controls

BiliSoft Light Box

The light box contains the LED module, a power supply, a cooling system, and an overheating protection. The universal power supply allows the unit to be supplied via any standard AC main power source at either 50 or 60 Hertz that has voltages in the range of 90 to 264 V~. The LED module produces a very narrow bandwidth of light with no appreciable amount of ultraviolet or infrared light. The light box is cooled by a fan, and a thermal cutout switch located on the LED module protects the light box from overheating. The LED module in the light box is activated only when the fiber optic cable is plugged into the system.

Component/Control	Function
	1. **Standby Switch –** Turns the unit on/off. The green light on the switch indicates that the standby switch is turned on and the unit is powered. 2. **Hour Meter –** The non-resettable hour meter runs whenever the fiberoptic light pad is illuminated. If the fiberoptic cable is not fully inserted into the light box, the LEDs are automatically shut off and the hour meter does not run. 3. **Unit Overheated Indicator –** When the red indicator light is on, the unit has overheated. See Troubleshooting Guide for more details. 4. **LED Module Failure Indicator –** When the red indicator light flashes, at least one of the three LED pairs has failed. See the Troubleshooting Guide for more details. 5. **Fiberoptic Light Pad Assembly Port -** Where the fiberoptic light pad assembly connects to the main unit. An LED shutoff switch inside the port automatically shuts off the LED module whenever the fiberoptic light pad assembly is disconnected. 6. **Air Vents –** For proper cooling it is important to keep the air vents clear of obstruction.

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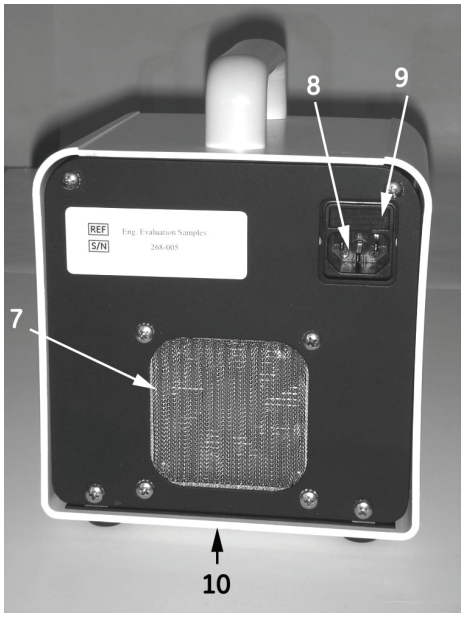
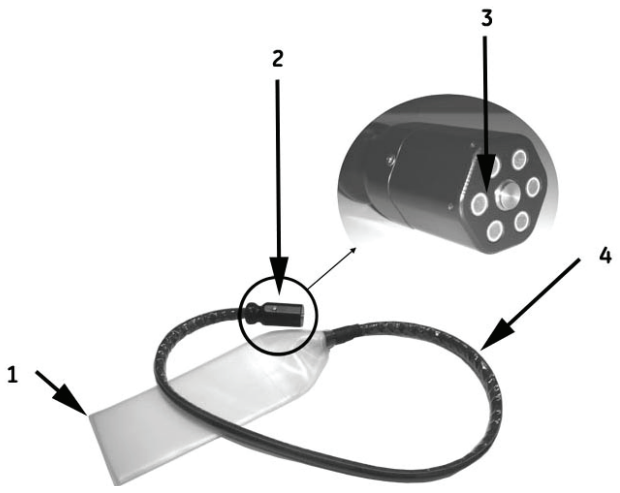
Component/Control	Function
	7. **Air Filter –** For proper cooling it is important to keep the air filter clear of obstruction. See the maintenance section of this manual for more details. 8. **Power Cord Receptacle** 9. **Fuse Cover -** Houses two power inlet fuses 10. **Mounting Bracket Holes –** Four holes on the bottom of the main unit are used to attach the optional mounting bracket. The mounting bracket can be positioned on the left or right side of the light box.

BiliSoft Fiberoptic Light Pad Assembly

The fiberoptic light pad comes in two sizes – large and small. The LED light source in the BiliSoft light box is focused on the fiberoptic lenses at the end of the fiberoptic cable connector. The fiberoptic cable contains plastic fibers that transmit light from the light box to the light pad. The light pad is constructed of these plastic fibers woven into a mat. This patented process produces a light pad that emits light over its entire surface. Average light intensity depends on the size of the light pad. See Specifications section for more details.

Component/Control	
	1. **Fiberoptic light pad** 2. **Fiberoptic cable connector** 3. **Fiberoptic lenses** 4. **Fiberoptic cable**

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WARNING:
Never place a baby directly on the bare fiberoptic light pad. The fiberoptic light pad should always be covered with a BiliSoft Pad Cover or BiliSoft Nest when used with the patient.

Soft Cover Options (Disposables)

The BiliSoft Pad Cover and BiliSoft Nest are designed for use with both premature and full-term infants. The BiliSoft Pad Cover and BiliSoft Nest are available in small and large sizes to accommodate whichever fiberoptic light pad is used.

BiliSoft Pad Cover	BiliSoft Nest
A flat cushioned cover with straps.	A cushioned cover with developmental positioning foot roll and straps.

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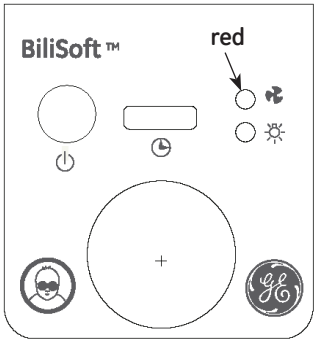
Chapter 4: Troubleshooting

CAUTION
Insulation on electrical wiring can deteriorate with age. Check for brittle or deteriorated insulation on the power cord before each use and all other electrical wiring while performing troubleshooting or replacement of internal components.

WARNING:
Whenever the unit is plugged in, AC power is present. Use caution when cover is removed.

NOTE: Potentiometers on the boards are set at the factory and are not to be adjusted in the field.

Troubleshooting Guide

Symptom	Troubleshooting Steps
A Unit Overheated Indicator light is on. 	1. Check that the air filter in the back of the unit and the air vents on either side of the unit are unobstructed. 2. Inspect the air filter. Clean or replace, if clogged. 3. Check that the environment that the unit is being operated in does not have ambient temperature above 35°C (95°F). 4. Turn off the power and allow the unit to cool. **NOTE:** It can take up to 10 minutes for the thermostat to reset. 5. Check that the fan is running with the power switch on (fan operates at low noise level- listen carefully). If the fan is not running, do the following: remove LED module, check connections J1 and J2, then check for 12V at pins 19 and 20 on J2 of the ribbon cable. If 12V present, replace the fan. 6. Slide unit out of housing and check the Control PCB connections. If properly connected, replace the Control PCB. 7. If the problem persists, replace the LED module.

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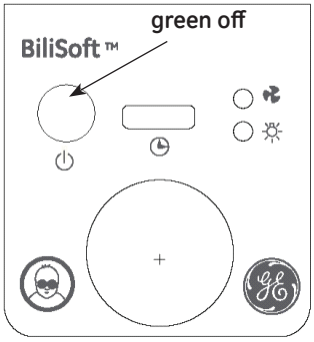
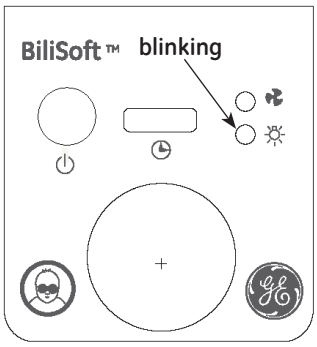
Symptom	Troubleshooting Steps
B No light output.	1. Check power connections and that the standby switch is on. Check that the fiberoptic pad connector is fully inserted. 2. Check that the green power indicator on the standby switch is lit. If indicator is not lit, see **C**. 3. Check if the Unit Overheated indicator is lit. If it is on, see **A**. 4. Check if the LED failure indicator is blinking. If it is blinking, see **D**. 5. Check if the fan is running. If so, replace the Control PCB. If not, remove cover and check Control PCB connections. 6. Disconnect J5 and check continuity through the fiberoptic pad connector switch (pins 1 and 2) with the fiberoptic pad connector inserted. If there is continuity, replace the Control PCB. If there is no continuity, replace the fiberoptic pad connector switch.
C Standby switch is on, but green indicator does not light. 	1. Check that the power cord is in good condition, and properly connected at both the light source and the line power source. 2. Check the fuses. Replace, if necessary. 3. Remove the cover and check the AC input to the Power Supply at connector J1. If there is no AC voltage present, replace the EMI filter or the AC harness as needed. 4. Check the 12V DC output of the Power Supply at connector J3 (pins 1 and 4). If there is no output, replace the Power Supply. if there is output, replace the power supply harness or Control PCB as needed.
D LED failure indicator light is blinking. 	1. Remove cover and check the Control PCB and LED PCB connections. 2. Check the voltage (5V is typical, but varies with array current demand) at pin 1 on U2 on the Control PCB and ground on pin 4 on J2 on the Power Supply. Repeat on U8 and U11 on the main control board. If voltage is present at all 3 test points, replace the LED module. If not, replace the Control PCB.

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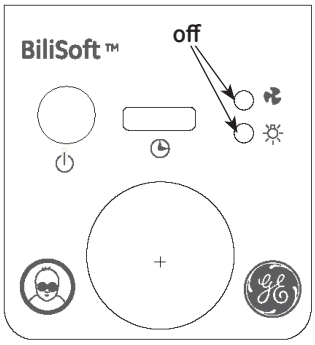
Symptom	Troubleshooting Steps
E Indicator lights not working. 	1. Confirm failure condition. 2. Remove cover and check all connections. 3. Check voltage across affected indicator LED pins on Display PCB. If voltage is present, replace the Display PCB. If no voltage is present, replace the Control PCB.
F Light output measurement is out of specification.	1. Check if the LED failure indicator is blinking. If it is blinking, see **D**. 2. Check that the fiberoptic pad connector is fully inserted and that nothing is obstructing the port. 3. Check the LED lenses inside the fiberoptic pad connector port for discoloration or damage. **NOTE:** See Operation and Maintenance Manual for approved cleaning procedure. 4. Check the fiberoptic light pad and fiberoptic lenses on the connector for discoloration or damage. **NOTE:** See Operation and Maintenance Manual for approved cleaning procedure. 5. Make sure that the irradiance measurement follows the procedure detailed in the Operation and Maintenance Manual. 6. Replace the LED module. 7. If the problem persists, replace the fiberoptic light pad. 8. If the problem persists, replace the Control PCB.
G Excessive fan noise	1. Check the air filter for obstruction. 2. Check the fan for obstruction. 3. Replace the fan.

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Symptom	Troubleshooting Steps
H Fiberoptic light pad, cable or connector is damaged.	1. Replace the fiberoptic light pad. **NOTE:** See Operation and Maintenance Manual for approved cleaning procedure.
J Fiberoptic pad connector switch not working	1. Check that the fiberoptic pad connector is fully inserted, and the standby switch is in the on position and the green indicator light is on. If indicator light is not lit, see **C**. 2. Remove cover and check the Control PCB and fiberoptic pad connector switch connections. 3. Check the continuity through the switch. If the switch is working, replace the Control PCB. If the switch is not working, replace the switch.
K Hour meter is not working.	1. If there is no light output, see **B**. 2. Check the connections on the Display PCB and the Control PCB. 3. Check pin 3 on the Display PCB ribbon cable for voltage. if voltage is present, replace the Display PCB. if no voltage is present, replace the Control PCB.

WARNING:
When handling the fiberoptic cable connector (during insertion, removal or positioning of the fiberoptic light pad) use caution to prevent the fiberoptic cable connector from dropping, which can damage the fiberoptic cable connector and/or injure the patient or caregiver.

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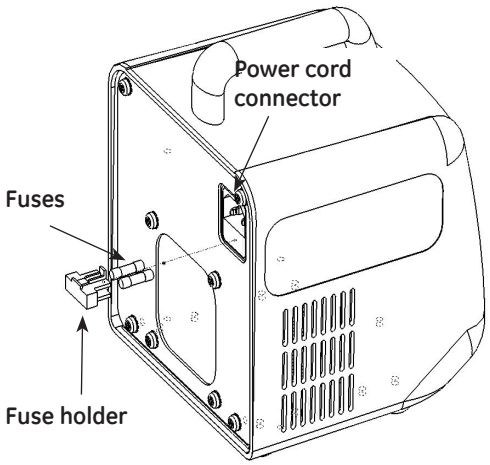
Chapter 5: Replacement/Checkout Procedures

⚠	**WARNING:** Whenever the unit is plugged in, AC power is present. Use caution when cover is removed.
⚠	**CAUTION** Anytime the unit is disassembled (back cover is removed) the electrical safety tests and light intensity measurement procedure must be performed to assure that the unit is functioning properly.

Fuse Replacement

Figure	Procedure
	1. Use a flat head screwdriver to pry open the fuse holder on the power cord connector (EMI filter). 2. Replace both fuses. 3. Snap fuse holder back in place.

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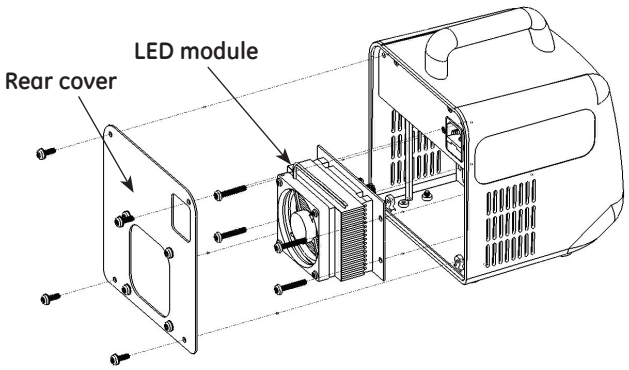
LED Module Replacement

Figure	Procedure
	 1. Use a Phillips screwdriver to remove the four screws and lockwashers that secure the rear access cover. 2. Remove the four LED module mounting screws. 3. Disconnect the ribbon cable J2. 4. Connect the ribbon cable to the new LED module and secure the LED module with the mounting hardware removed in step 2. 5. Reinstall the rear access cover. 6. Record the time from the hour meter in order to accurately track the LED module life.

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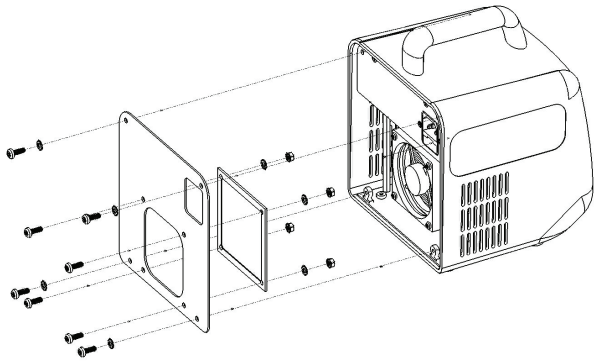
Air Filter Cleaning/Replacement

Figure	Procedure
	1. The air filter can be vacuumed without removing it. 2. To remove the air filter, use a Phillips screwdriver to remove the four screws and lockwashers that secure the rear access cover. 3. Use a Phillips screwdriver and adjustable wrench or nut driver to remove the 4 screws, lockwashers, and nuts retaining the air filter. 4. Clean or replace the air filter as needed. 5. Attach the air filter using the hardware removed above in step 2. 6. Reinstall the rear access cover.

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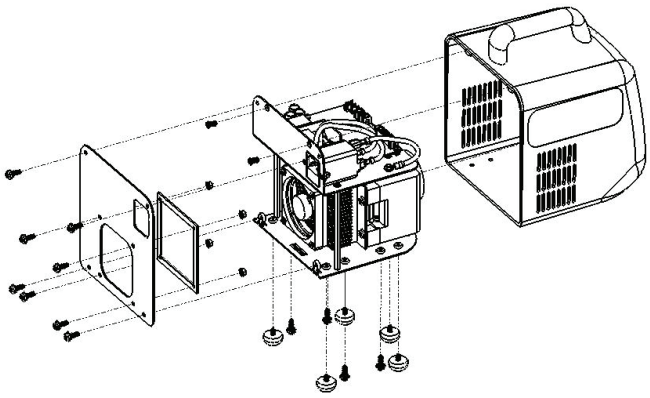
Accessing/Replacing Other Internal Components

Figure	Procedure
	 1. Use a Phillips screwdriver to remove the four screws and lockwashers that secure the rear access cover. 2. Use a Phillips screwdriver to remove the five foot pads on the bottom of the unit. Remove the optional mounting bracket if installed. 3. Use a Phillips screwdriver to remove the two screws on the back of the unit at the very top of the sheet metal plate. 4. Carefully slide the inside chassis out from within the cover. 5. Use the exploded views in the Spare Parts section of this manual for replacement of individual components. 6. When completed, slide the inside chassis back into the cover being careful not to pinch any wires. 7. Reverse the steps above to close up the unit.

Checkout Procedures

CAUTION
Anytime the unit is disassembled (back cover is removed) the electrical safety tests and light intensity measurement procedure must be performed to assure that the unit is functioning properly.

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Electrical Safety Checkout Procedure

Use approved equipment and techniques to test the unit's leakage current and ground continuity. Follow the directions supplied by the test equipment manufacturer to verify the following:	
Leakage Current	Less than **300** microamperes measured at any exposed metal surface.
Ground Resistance Check	Measure the resistance between the ground pin on the line cord plug and exposed metal of the light box. The ground resistance must be less than **0.1** ohms.

Light Intensity Checkout Procedure

1. Fully insert the fiberoptic light pad connector into the light box.

> **WARNING:**
> When handling the fiberoptic cable connector (during insertion, removal or positioning of the fiberoptic light pad) use caution to prevent the fiberoptic cable connector from dropping, which can damage the fiberoptic cable connector and/or injure the patient or caregiver.

2. Connect the power cord to the back of the unit, then to an appropriately grounded power source.

3. Turn the BiliSoft LED Phototherapy System on using the standby switch on the front of the unit and allow it to run for five (5) minutes.

4. Place the fiberoptic light pad on a flat surface. Do not place the fiberoptic light pad inside of the BiliSoft Pad Cover or BiliSoft Nest at this time.

5. Use a properly-calibrated Ohmeda Medical BiliBlanket Meter II to check the irradiance level of the unit using the template printed on the fiberoptic light pad. There are two ways to check the irradiance level - a center-row quick check, which provides approximate irradiance values, and the more comprehensive 6-point (for small fiberoptic light pad) or 9-point (for large fiberoptic light pad) check, which provides more accurate irradiance values.

To perform the center-row check, measure the irradiance level at each point on the center row using the template printed on the fiberoptic light pad. For a small pad, the center row points are C and D. For the large pad, the center row points are D, E and F. Calculate the average of the center row irradiance measurements. Use the first column of the chart below to determine if the minimum acceptable center-row irradiance has been met. If the average of the light meter readings meets or exceeds the acceptable minimum irradiance, then the unit is ready for use.

If the meter readings are lower than these values, perform the more comprehensive 6-point (small pad) or 9-point (large pad) check. Measure the irradiance level at each point using the template printed on the fiberoptic light pad. Calculate the average of the irradiance measurements. Use the second column of the chart below to determine if the average irradiance is within specification. If the average irradiance is outside of the acceptable range, see the troubleshooting section of this manual.

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	Center-Row Irradiance* (bare fiberoptic light pad) $\mu W \bullet cm^{-2} \bullet nm^{-1}$	**Average Irradiance *** (bare fiberoptic light pad) (+/- 25%) $\mu W \bullet cm^{-2} \bullet nm^{-1}$
Large Pad	(D + E + F)/3 ≥ **48.5**	(A + B + C + D + E + F + G + H + I)/9 = **49**
Small Pad	(C + D)/2 ≥ **70.0**	(A + B + C + D + E + F) /6 = **70**

* Using an Ohmeda Medical BiliBlanket Meter II

NOTE: When the BiliSoft fiberoptic light pad is inserted into a BiliSoft Pad Cover or BiliSoft Nest, the nominal spectral irradiance is:

- 35 $\mu W \bullet cm^{-2} \bullet nm^{-1}$ (large pad)
- 50 $\mu W \bullet cm^{-2} \bullet nm^{-1}$ (small pad)

Once the check is complete, turn the unit off. The unit is ready for use.

It is recommended that the BiliSoft LED Phototherapy System be checked with the Ohmeda Medical BiliBlanket® Meter II for desired therapeutic intensity before use with each patient.

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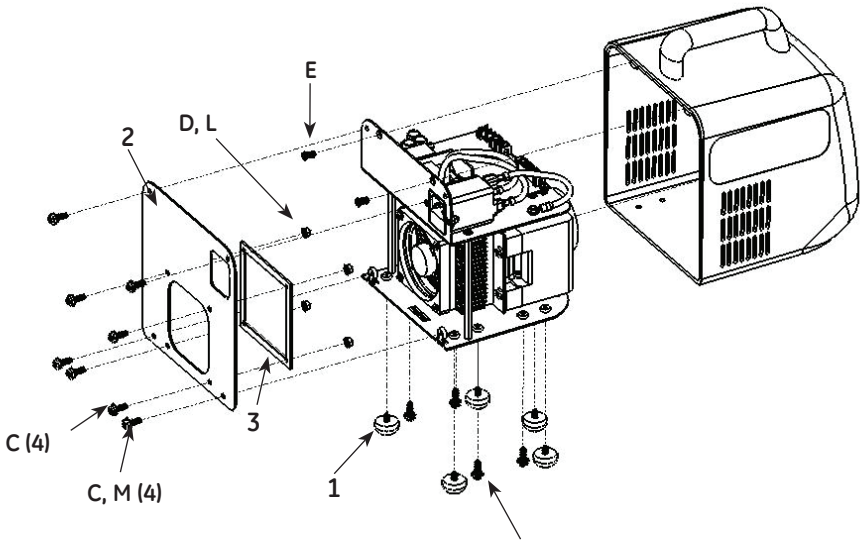
Part Numbers	Figure 6-1
1. Foot Pad Kit **M1098508** includes 5 foot pads 2. Back Cover Kit **M1110057** includes back plate and label. **NOTE:** When replacing the back plate, the old SN insert must be retained and transferred to the new back plate 3. Air Filter **M1098511**	 **Mounting Bracket screws (4)** (included in optional Mounting Bracket Kit M1097110) *Lettered hardware kits listed at end of parts section*

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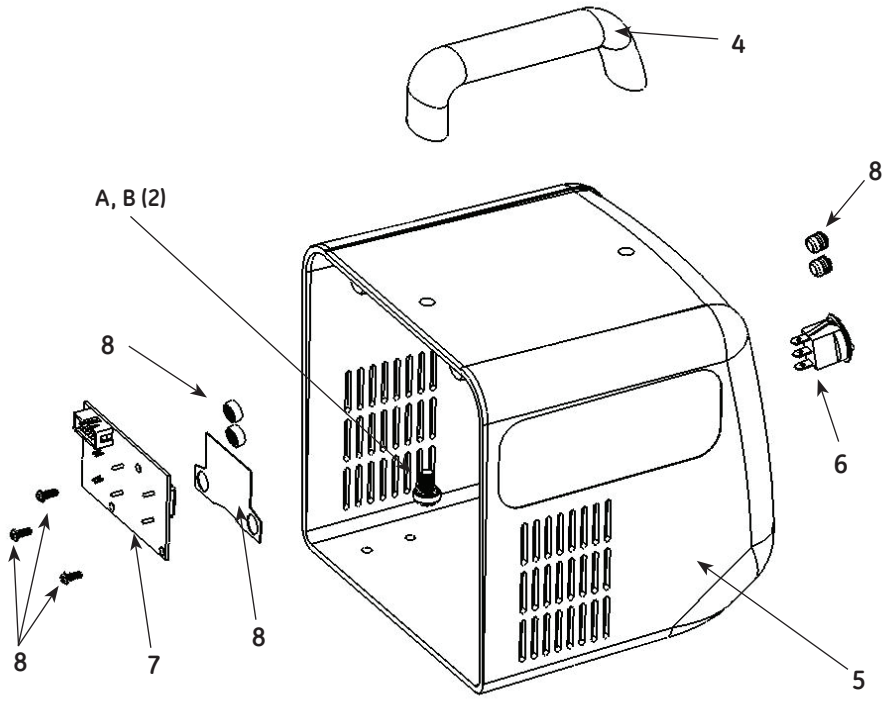
Part Numbers	Figure 6-2
4. Handle **M1098507** 5. Enclosure Kit **M1098512** includes enclosure, side label set. **NOTE:** Proper language label must be selected from the label set and applied to the product 6. Standby Switch **M1110058** 7. Display PCB **M1120981** 8. Bezel/Lens Kit **M1120982** includes bezel, lenses (2), lens retainers (2)	 *Lettered hardware kits listed at end of parts section*

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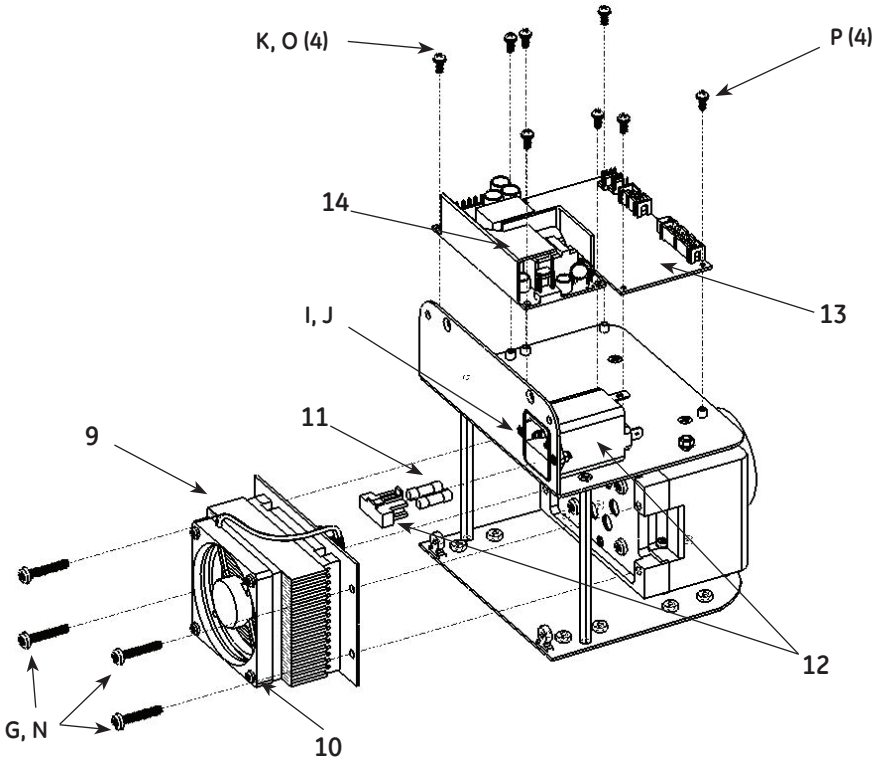
Part Numbers	Figure 6-3
9. LED Module Kit **M1098188** includes item #10, heatsink, and LED board 10. Fan Kit **M1098497** includes mounting screws (4)) 11. Fuse Kit **6600-0730-214** includes 2 fuses (T3.15A @ 250V~, slo-blo type) 12. EMI Filter **M1098505** fuses sold separately 13. Control PCB **M1185734** * * Refer to Note 1 after this table. 14. Power Supply **M1098503**	 *Lettered hardware kits listed at end of parts section*

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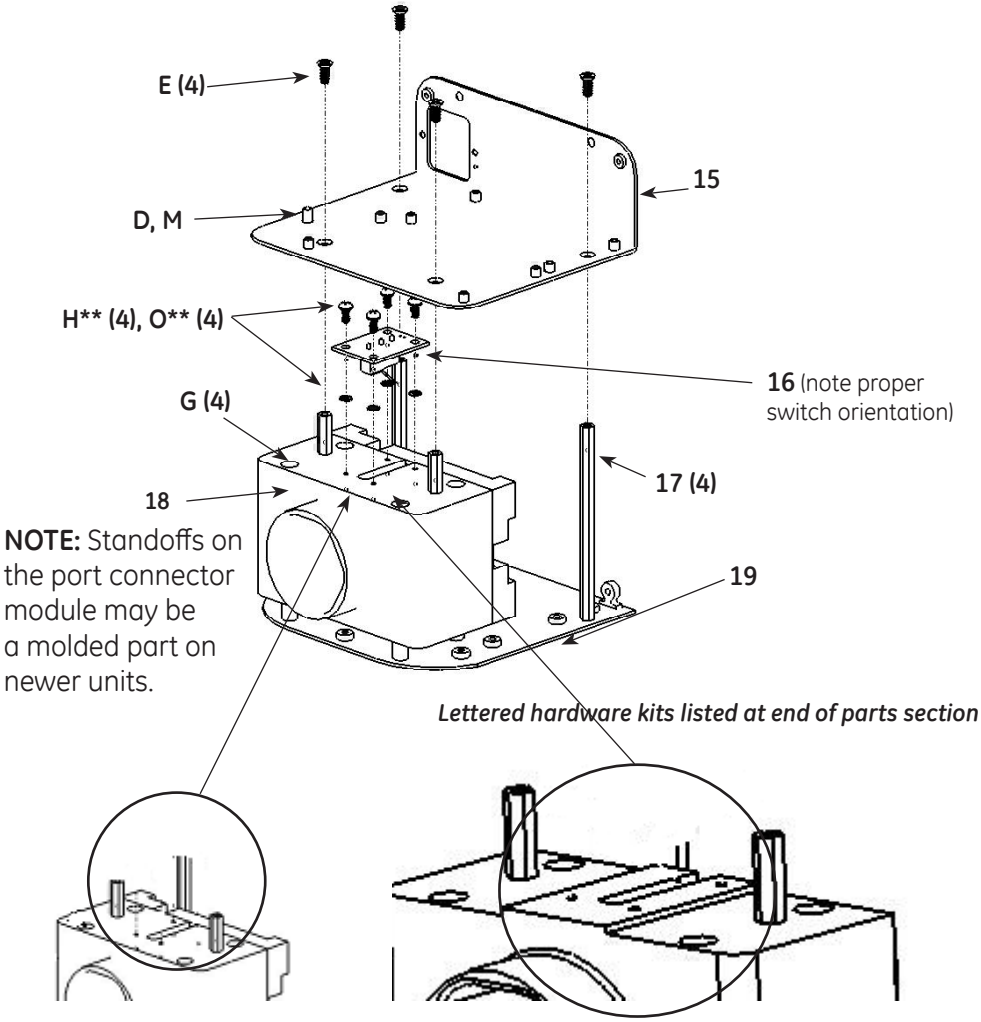
Part Numbers	Figure 6-4
15. Top Plate Kit **M1110054** includes ground label 16. LED Shutoff Switch Kit **M1185735** * * Refer to Note 1 after this table. ** For the old style pad connector, the external star washers are placed under the board during assembly to provide proper clearance. 17. Standoff Kit **M1120983** includes 2 large standoffs and 2 small standoffs 18. Pad Connector Module **M1120994** Includes Port connector, lens, Lens holder plate, and magnet 19. Bottom Plate Kit **M1120993** **NOTE:** When replacing the bottom plate, the old SN should be written on the blank label	 **Old Style Pad Connector** (units with serial number HFAL50306 or lower) The external star washers (O) are placed under the board as shown above during assembly to provide the proper clearance **New Style Pad Connector (with raised switch mounting surface)** (units with serial number HFAL50307 or higher or if pad connector has been replaced) The external star washers (O) shown above are not needed with the new style pad connector.

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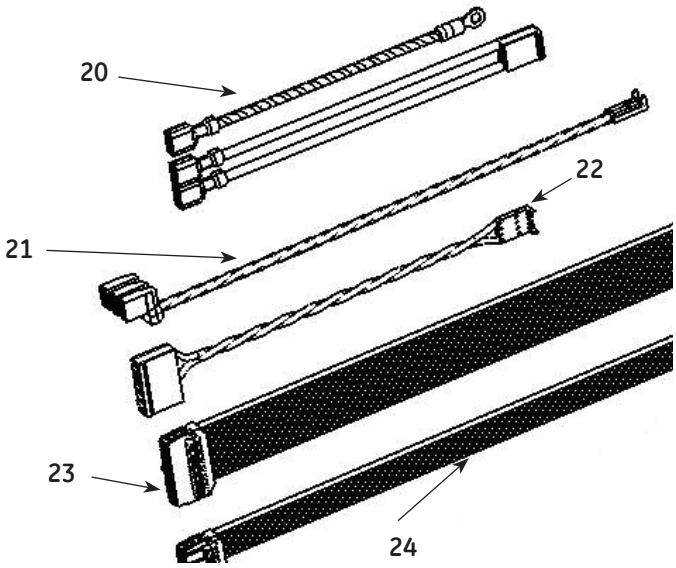
Part Numbers	Figure 6-5
20. Power Supply AC harness **M1098500** 21. Standby Switch Harness **M1185737*** 22. Power Supply Harness **M1185736*** * Refer to Note 1 after this table. 23. LED board harness **M1098501** 24. Front Panel harness **M1098502**	

NOTE 1: Service Kit Package for Control PCA

M1185738 is the Service Kit Package for Control PCA, and it contains the following parts:

Part Description	Part Number	Quantity
Control PCB	M1185734	1
LED Shutoff Switch Kit	M1185735	1
Power Supply Harness	M1185736	1
Standby Switch Harness	M1185737	1

Bilisoft units manufactured with the new connector design can be distinguished from the old-design units based on their serial number. That is, units with serial number equal or greater than HFAN50501 are new-design units. Old-design units have serial numbers less than HFAN50501. If any of the four parts (M1185734, M1185735, M1185736, M1185737) need to be replaced for any reason, replace as follows:

- For units with serial numbers less than HFAN50501, order the service kit (M1185738) to update all four parts to the latest design.
- For units with serial number equal to or greater than HFAN50501, each part can be ordered and replaced individually.

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Hardware Kits (sold in packs of 10)

A	**M1098517**	M6 10mm, Phillips Machine screw
B	**M1120985**	M6, External Tooth Lock Washer
C	**M1098616**	M4 12mm, Phillips Machine Screw
D	**M1120986**	M4 Nut
E	**M1098520**	M4 10mm, Phillips Machine Screw, Flat Head
F	**M1120992**	M3 8mm Thread-Forming Screws, Phillips
G	**M1098519**	M4 25mm, Phillips Machine Screw
H	**M1098518**	M3 8mm, Phillips Machine Screw
I	**M1098528**	M3 10mm, Phillips Machine Screw, Flat Head
J	**M1098529**	M3, Nut W/External Tooth Lock Washer
K	**M1098530**	M3 5mm, Phillips Machine Screw
L	**M1126473**	M4 Internal Tooth Lock Washer
M	**M1098527**	M4, External Tooth Lock Washer
N	**M1126472**	M4 Split Lock Washer
O	**M1126469**	M3 external tooth lock washer
P	**M1126471**	M3 5mm, Phillips Machine Screw, Plastic

Touch-up Paint for Cool-Gray 3 paint on the cover is available as M1128293.

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Chapter 7: Accessories

Accessories	Stock Number
BiliSoft Fiberoptic Pad, Small	M1093118
BiliSoft Fiberoptic Pad, Large	M1093119
BiliSoft Pad Cover, Disposable, Small (Box of 50)	M1093120
BiliSoft Pad Cover, Disposable, Small (Box of 20)	M1097108
BiliSoft Pad Cover, Disposable, Large (Box of 50)	M1093121
BiliSoft Pad Cover, Disposable, Large (Box of 20)	M1097109
BiliSoft Nest, Disposable, Small (Box of 15)	M1093122
BiliSoft Nest, Disposable, Large (Box of 15)	M1093123
BiliSoft Carrying Case	M1110051
Ohmeda Mobile Stand (mounting brackets must be ordered separately)	6700-0025-800
Giraffe Spot PT Lite Roll Stand (mounting brackets must be ordered separately)	6600-0894-216
Bracket, Ohmeda Mobile Stand, female (for mounting to the Ohmeda mobile stand - order male bracket separately)	6700-0014-800
Bracket, Dovetail Rail, female (for mounting to an Ohmeda dovetail rail or Giraffe Spot PT Lite roll stand – order male bracket separately)	6600-0031-900
BiliSoft Mounting Bracket, male (mounts the BiliSoft to Ohmeda mobile stand, Giraffe Spot PT Lite roll stand, or Ohmeda dovetail rail – order the appropriate female bracket separately)	M1097110
Ohmeda Medical BiliBlanket Meter II	6600-0198-900
Operation and Maintenance Manual, English 8.5x11 (USA)	M1110147
Operation and Maintenance Manual, English A4 (UK)	M1133866
Operation and Maintenance Manual, French	M1110476
Operation and Maintenance Manual, Spanish	M1110480
Operation and Maintenance Manual, Italian	M1110482
Operation and Maintenance Manual, Japanese	M1110484
Operation and Maintenance Manual, Dutch	M1110619

WARNING:
The use of accessories, replacement parts or power cords other than those specified by the manufacturer may affect the performance of the unit and could result in damage to the unit or unsafe operating conditions.

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Accessories	Stock Number
Operation and Maintenance Manual, German	M1110625
Operation and Maintenance Manual, Swedish	M1110628
Operation and Maintenance Manual, Portuguese	M1110632
Operation and Maintenance Manual, Polish	M1110645
Operation and Maintenance Manual, Russian	M1110986
Operation and Maintenance Manual, Finnish	M1110988
Operation and Maintenance Manual, Greek	M1110990
Operation and Maintenance Manual, Danish	M1110993
Operation and Maintenance Manual, Turkish	M1110997
Operation and Maintenance Manual, Norwegian	M1129265
Operation and Maintenance Manual, Czech	M1129267
Operation and Maintenance Manual, Estonian	M1129269
Operation and Maintenance Manual, Lithuanian	M1129289
User Reference Card, English	M1097124
User Reference Card, French	M1097147
User Reference Card, Spanish	M1097152
User Reference Card, Italian	M1097156
User Reference Card, Japanese	M1097161
User Reference Card, Dutch	M1097182
User Reference Card, German	M1097244
User Reference Card, Swedish	M1097246
User Reference Card, Portuguese	M1110999
User Reference Card, Polish	M1111005
User Reference Card, Russian	M1111047
User Reference Card, Finnish	M1111050
User Reference Card, Greek	M1111054
User Reference Card, Danish	M1111057
User Reference Card, Turkish	M1111059
User Reference Card, Norwegian	M1128867

WARNING:
The use of accessories, replacement parts or power cords other than those specified by the manufacturer may affect the performance of the unit and could result in damage to the unit or unsafe operating conditions.

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Accessories	Stock Number
User Reference Card, Czech	M1128871
User Reference Card, Estonian	M1128873
User Reference Card, Lithuanian	M1128888
Power Cord, North America	6600-0730-207
Power Cord, Australian	6600-0574-614
Power Cord, United Kingdom	6600-0744-200
Power Cord, CE	6600-0745-200
Power Cord, Danish	M1093124
Power Cord Indian	M1153026
Power Cord Israel	M1177962
Power Cord South African	M1177960
Power Cord Swiss	M1171635
Power Cord Philippine	M1194543

WARNING:
The use of accessories, replacement parts or power cords other than those specified by the manufacturer may affect the performance of the unit and could result in damage to the unit or unsafe operating conditions.

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Chapter 8: Specifications

NOTE: All specifications are nominal and are subject to change without notice.

Electrical Specifications

Input	1.5A @ 100 – 240 V~, 50/60 Hz
Fuses	T3.15A @ 250V~, slo-blo type (qty. 2)
Leakage Current	< 300 µA @ 264 V~
Ground impedance	< 0.1 ohm from ground pin of the power inlet module to any exposed metal surface.

Environmental Operating Conditions

Ambient temperature	+10°C to +35°C (50 to 95°F).
Humidity	10% to 90% RH non-condensing
Atmospheric pressure	70 kPa to 106 kPa

Storage Requirements

Temperature	-40°C to +70°C (-40 to 158°F).
Humidity	0% to 100% RH non-condensing
Atmospheric pressure	50 kPa to 106 kPa

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Performance Specifications

Spectral Irradiance (bare fiberoptic pad)* *Using an Ohmeda Medical BiliBlanket Meter II	Large Fiberoptic Pad – 49 µW•cm^{-2}•nm^{-1} (+/- 25%) 9-point check Small Fiberoptic Pad – 70 µW•cm^{-2}•nm^{-1} (+/- 25%) 6-point check **NOTE:** When the BiliSoft fiberoptic light pad is inserted into a BiliSoft Pad Cover or BiliSoft Nest, the nominal spectral irradiance is 35 µW•cm^{-2}•nm^{-1} (large pad) and 50 µW•cm^{-2}•nm^{-1} (small pad)
Wavelength	430-490 nm (peak 440-460 nm)
LED module estimated life**	Under continuous use, tested at room temperature, a typical LED module will run for approximately 8,000 to 10,000 hours before the light intensity drops 25%.
Sound level	< 44 dB(A) at 1 meter
X-ray	X-ray compatible

**The LED module life may vary when used in the actual clinical environment. Factors such as duty cycle and ambient temperature may impact the life of the LED module. Measure the irradiance and replace the LED module when the BiliSoft system is below specifications.

Physical Specifications

Light box (W × H × L)	16.5 × 21 × 16.5 cm
Light box weight (excluding fiberoptic pad)	< 2.5 kg
Fiberoptic Pad weight	< 1.1 kg
Fiberoptic light pad, small	15 × 30 cm (light-emitting area)
Fiberoptic light pad, large	25 × 30 cm (light-emitting area)
Fiberoptic cable length	137 ± 5 cm

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Regulatory Standards

IEC Type B equipment. IEC Class 1 (continuous operation) FDA Class II	**Product certified to the following standards:** EN60601-1; EN60601-1-2; EN60601-2-50; ISO 10993-5; ISO 10993-10; UL 60601-1; CSA C22.2 No 601.1-M90; IEC 60601-1-8; BS EN 980; 16CFR Part 1632.6 (for BiliSoft Pad Covers and BiliSoft Nests)

CE 0086

GE Healthcare has declared that this product conforms with the European Council Directive 93/42/EEC Medical Device Directive when it is used in accordance with the instructions provided in the Operation and Maintenance Manual.

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

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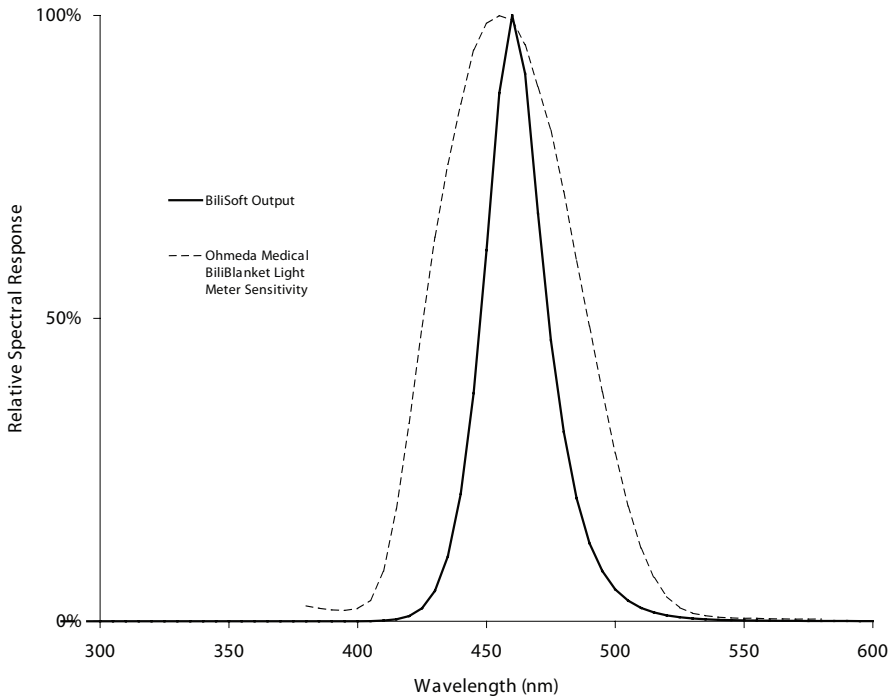
The following information is provided for compliance to IEC 60601-2-50.



Average Total Irradiance for Bilirubin (measured with a spectroradiometer between 400-550 nm)
= 10.5 mW•cm^{-2} (bare fiberoptic pad, small)
= 7.9 mW•cm^{-2} (bare fiberoptic pad, large)

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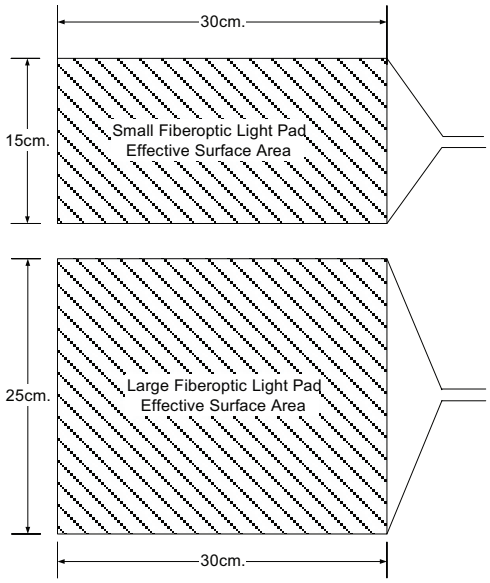

EMC Guidance

Safety Standards: IEC 60601-1, IEC 60601-2-50, EMC Standards IEC 60601-1-2

Table 1

Guidance and manufacturer's declaration - electromagnetic immunity
The BiliSoft Phototherapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the BiliSoft Phototherapy System should assure that it is used in such an environment.

Immunity Test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	+/- 6kV contact +/- 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2kV for power supply lines. +/- 1kV for input/output lines.	+/- 2kV for power supply lines. +/- 1kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital or domestic environment.

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Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic environment-guidance
Surge IEC 61000-4-5	+/- 1kV differential Mode. +/- 2kV common mode.	+/- 1kV differential Mode. +/- 2kV common mode.	Mains power quality should be that of a typical commercial or hospital or domestic environment.
Voltage dips, shorts interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ut(>95 % dip in Ut) for 0.5 sec 40 %tUt (60 % dip in Ut) for 5 cycles 70 % Ut(30 % dip in Ut) for 25 cycles <5% Ut(>95% dip in Ut) for 5 sec.	<5 % Ut(>95 % dip in Ut) for 0.5 sec 40 %Ut(60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec.	Mains power quality should be that of a typical commercial or hospital or domestic environment. If the user of the BiliSoft Phototherapy System requires continued operation during power mains interruption, it is recommended that the BiliSoft Phototherapy System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field environment IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital or domestic environment.

NOTE: Ut is the a.c. mains voltage prior to application of the test level.

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Table 2

Guidance and manufacturer's declaration - electromagnetic immunity			
The BiliSoft Phototherapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the BiliSoft Phototherapy System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment-guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 KHz to 80 KHz 3 V/m 80 Mhz to 2.5 Ghz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BiliSoft Phototherapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [1.1667]\sqrt{P}$ 150 kHz to 80 MHZ $d = [1.1667]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.33]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in meters (m). Field strengths for fixed RF transmitters as determined by an electromagnetic site survey (see Note 2 a) should be less than the compliance level in each frequency range (see Note 2 b). Interference may occur in the vicinity of equipment. Marked with the following symbol:

NOTE 1: At 80 MHz to 800 MHz, the frequency range applies.

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NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters such as base stations for radio, cellular/cordless telephones and land mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BiliSoft Phototherapy unit is used exceeds the applicable RF compliance level above, the BiliSoft Phototherapy unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BiliSoft Phototherapy unit.

b. Over the frequency range 150 KHz to 80 MHz field strengths should be less than 3 V/m.

Table 3

Recommended separation distance between portable and mobile RF communications equipment and the BiliSoft Phototherapy System			
The BiliSoft Phototherapy System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BiliSoft Phototherapy System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communica¬tions equipment (transmitters) and the BiliSoft Phototherapy System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHZ $d = [1.1667] \sqrt{P}$	**80 MHz to 800 MHz** $d = [1.1667] \sqrt{P}$	**800 MHz to 2.5 GHz** $d = [2.33] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12.0	12.0	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance (*d*) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Table 4

Guidance and manufacturer's declaration – electromagnetic emissions		
The BiliSoft Phototherapy System is intended for use in the electromagnetic environment specified below. The customer or the user of the BiliSoft Phototherapy System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment- guidance**
RF emissions CISPR 11	Group 1	The BiliSoft Phototherapy System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The BiliSoft Phototherapy System is suitable for use in all establishments, including domestic establishments and and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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Appendix Additional Safety Information

Statements

This device should only be operated by personnel trained in its operation and familiar with the risks and benefits of this type of device.

WARNING:
To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.

WARNING:
The user or service staff should dispose all the waste properly as per federal, state, and local waste disposal regulations. Improper disposal could result in personal injury and environmental impact.

No additional tasks are required to power down the device after clinical use, other than turning off the unit.

Isolation of the unit from the supply mains can be achieved by unplugging the device.

WARNING:
Electrical shock hazard: Before servicing, always unplug the unit from wall power.

Phototherapy light can hinder clinical observations by masking skin color changes, such as cyanosis.

This device shall be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of infant phototherapy equipment use.

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Symbols

The following symbol appears on the unit:

Symbol	Description
	Consult accompanying documents.
	Do not place items in radiant heat path.
	Cover the patient's eyes during phototherapy.

Checkout Procedures

Examine the unit for any missing or damaged labels.

Specifications

The product is designed to meet a life span of 7 years. However, with proper maintenance and repairs, the service life can be extended as long as service parts are available.

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Warranty

This Product is sold by GE Healthcare under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of this Product directly from GE Healthcare or GE Healthcare's Authorized Dealers as new merchandise and are extended to the Buyer thereof, other than for the purpose of resale. For a period of twelve (12) months for the light box and the pad from the date of original delivery to Buyer or to Buyer's order, but in no event for a period of more than two years from the date of original delivery by GE Healthcare to an GE Healthcare Authorized Dealer, this Product, other than its expendable parts, is warranted to be free from functional defects in materials and workmanship and to conform to the description of the Product contained in the operation manual and accompanying labels and/or inserts, provided that the same is properly operated under the conditions of normal use, that regular periodic maintenance and service is performed and that replacements and repairs are made in accordance with the instructions provided. This same warranty is made for a period of thirty (30) days with respect to expendable parts. The foregoing warranties shall not apply if the Product has been repaired other than by GE Healthcare or in accordance with written instructions provided by GE Healthcare, or altered by anyone other than GE Healthcare, or if the Product has been subject to abuse, misuse, negligence, or accident. GE Healthcare's sole and exclusive obligation and Buyer's sole and exclusive remedy under the above warranties is limited to repairing or replacing, free of charge, at GE Healthcare's option, a Product, which is telephonically reported to the nearest GE Healthcare Regional Service Office and which, if so advised by GE Healthcare, is thereafter returned with a statement of the observed deficiency, not later than seven (7) days after the expiration date of the applicable warranty, to the designated GE Healthcare Service Center during normal business hours, transportation charges prepaid, and which, upon GE Healthcare's examination, is found not to conform with above warranties. GE Healthcare shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages, or special damages. There are no express or implied warranties that extend beyond the warranties hereinabove set forth. GE Healthcare makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

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CE 0086 BiliSoft™ LED Phototherapy System
Service Manual
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Printing instructions:
Black on white
8.5" x 11" paper size
Two (2) sides print
Three (3) hole punch
Stapled